

Gish, et al.  
Application No.: 09/747,371  
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the "longer" sequence in the aligned region. The "longer" sequence is the one having the most actual residues in the aligned region (gaps introduced by WU-BLAST-2 to maximize the alignment score are ignored).

**Title**

Please change the title of the application to: Novel Methods for Detection and Diagnosis of Breast Cancer.

IN THE CLAIMS:

Please amend claims 32, 33, 35, and 38 as indicated below. Also, please add claim 39.

32. (Amended) A method for detecting a breast cancer cell in a patient, the method comprising:

(i) detecting a nucleic acid encoding an amino acid sequence at least 80% identical to SEQ ID NO:1 in a sample from the patient, and

(ii) comparing expression levels of the nucleic acid in the sample from the patient to expression levels of the nucleic acid in a normal tissue sample,

wherein an increase in expression of the nucleic acid in the sample from the patient indicates the presence of a breast cancer cell in the patient.

33. (Amended) The method of claim 32, wherein the sample from the patient comprises isolated nucleic acids.

35. (Amended) The method of claim 32, wherein the sample from the patient is breast tissue.

38. (Amended) The method of claim 32, wherein said detecting step is carried out by utilizing a biochip comprising a sequence at least 80% identical to SEQ ID NO:1.

39. (New) The method of claim 32, wherein the nucleic acid is at least 95% identical to SEQ ID NO:1.

### REMARKS

#### **The Invention**

The invention is based in part on the discovery that high expression of BCO2 is correlated in a statistically significant manner with the existence of breast cancer. Thus, BCO2 over-expression can be diagnostic of the presence of a breast cancer cell in a sample from a patient.

#### **Status of the Claims**

Claims 1-38 are pending in this application. Claims 1-6 and 8-31 are withdrawn from consideration. Claims 32-38 are rejected.

Claims 32-38 are rejected under 35 U.S.C. §112, first paragraph containing subject matter that which was not described in such a way as to enable one skilled in the art to make and use the invention.

Claims 32-38 are also rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to point out and distinctly claim the subject matter the Applicant regards as the invention.

#### **Support for the Amendments to the Claims**

Support for the amendments to claim 32 are found in the specification on page 31, lines 30-32 wherein it is stated: "A breast cancer gene can qualitatively have its expression altered including activation ... in, for example normal versus breast cancer tissue". On page 32, lines 13-16 the specification recites that: "the amount of gene